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A5R
(71) Applicant
Telectronics Pty Ltd
(Australia–New South Wales)
14 Mars Road
Lane Cove
2066 NSW
Australia
(72) Inventor
Tibor A Nappholz
(74) Agent and/or Address for Service
A A Thornton and Co
Northumberland House
303–306 High Holborn
London
WC1V 7LE

(54) Three-electrode pacing/sensing heart pacer

(57) There is disclosed a pacing/sensing electrode configuration for a heart pacer. A bipolar lead is utilized for sensing purposes, the sense amplifier responding to the potential difference which appears across the stimulating and indifferent electrodes. Pacing pulses are generated by causing a current flow between the stimulating electrode and the pacer case, rather than between the stimulating electrode and the indifferent electrode. In this way, the advantages of both unipolar-lead pacing and bipolar-lead sensing can be achieved in the same pacer.

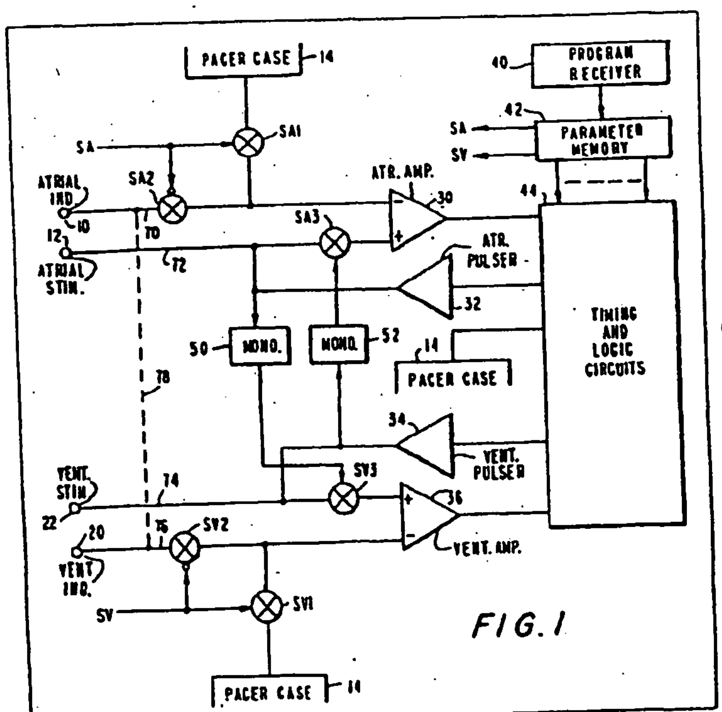

FIG. 1

The drawing(s) originally filed was/were informal and the print here reproduced is taken from a later filed formal copy.

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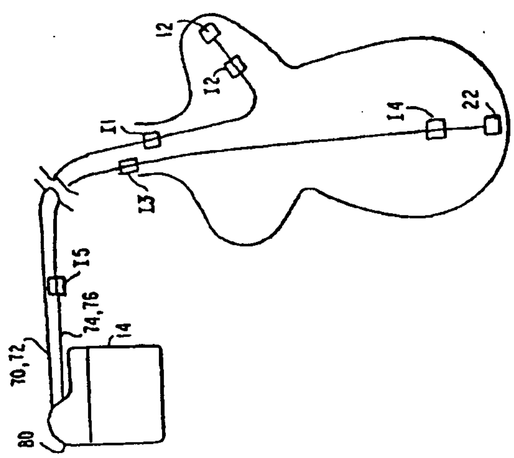
FIG. 2



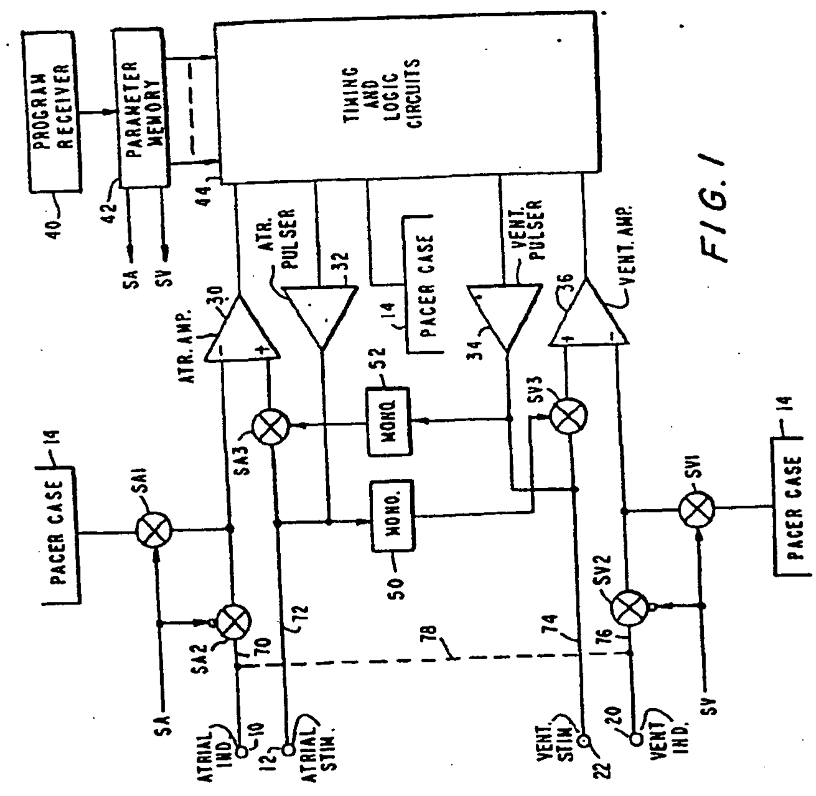


FIG. 1

SPECIFICATION

Three-electrode pacing/sensing heart pacer

This invention relates to cardiac pacers, and more particularly to an arrangement which provides for different pacing and sensing electrode circuits.

In most modern-day heart pacers, a sensing capability is provided along with a pacing capability. Whether the pacer is a single-chamber or dual-chamber device, the pacer generally has to sense heart activity in any chamber which is paced. A stimulating electrode is fixed in the wall of the heart chamber. In some cases, an indifferent electrode is also coupled to the wall of the heart chamber. But in other cases, an indifferent electrode is not used at all; instead, the metallic case of the pacer serves as the "indifferent" voltage reference.

The present invention is applicable to both single-chamber and dual-chamber pacers. Although disclosed in the context of a dual-chamber device, it is to be understood that the same principles of operation are applicable to a single-chamber device since the electrode arrangement to be described below is applicable to each of the two chambers. Generally speaking, the term "electrode lead" refers to the wire (usually having a helical shape) which is extended from the pacer unit to the heart; the term "electrode" itself refers to the tip which is attached to the electrode lead and is coupled to the heart chamber. A "unipolar lead" is a plastic sheath which includes a single helically-wound electrode lead; a "bipolar lead" is one which includes two electrode leads, with one lead usually being wound in a helical shape around the other, and with insulation being provided between them. At each end of a bipolar lead, there is often an annular ring on the outside. The two annular rings are connected to one of the internal electrode leads, with each end of the bipolar lead having a tip which is connected to the other electrode lead. Examples of unipolar and bipolar leads are shown, for example, in U.S. Patent No. 4,301,805, issued on November 24, 1981 and entitled "Cardiac Pacer Connector System". When a unipolar lead has been used in the prior art, the potential for pacing the heart chamber has been applied between the single electrode lead and the case; similarly, the sensing of heart activity has been based upon the detection of a potential difference between the same electrode lead and the case. When a bipolar lead has been used in the prior art, the pacing potential has appeared between the stimulating and indifferent wire terminations at the distal end of the two-wire lead; similarly, any heart chamber activity which is sensed has been based upon the detection of a potential difference between the two wire terminations.

Neither arrangement is entirely satisfactory. It is better to "pace from the case", i.e., not to use an indifferent electrode for pacing, in order to prevent anodic stimulation; pacing over a bipolar lead, with two pacing electrodes being placed in the ventricle, can give rise to fibrillation. Another reason for favoring using the case as the indifferent electrode when it comes to pacing is that pacing with a bipolar lead will fail if either lead loses contact with the wall of the ventricle. There is a smaller likelihood of a break in the life-support link if the case is used as the indifferent electrode during pacing.

On the other hand, it is more advantageous to sense heart activity with the use of a bipolar lead. Typical signals which are sensed are very low in amplitude, and electrical interference is an always-present problem. Such interference can arise from myopotentials generated around the pacer case due to local muscle activity, and general muscle tremors due to Parkinson's Disease and other nervous disorders. There is also a problem with external interference from electromagnetic sources. The degree of interference is determined by the location of the "indifferent" relative to the stimulating electrode. If the indifferent, or reference point, is placed very close to the stimulating electrode (which functions as a sensing electrode), in the heart of just outside of it, interference may be reduced considerably. This is due to the fact that there are fewer sources of potential between two closely spaced metallic terminations than there are between the same two terminations when they are widely separated.

With ventricular pacers, a typical sensitivity for the sensing circuit is 2–3 millivolts (referenced to a 25-millisecond triangular pulse, as is known in the art). With atrial sensing, the sensitivity has to be increased so that signals in the 0.2–0.5 millivolt range can be detected. Thus the interference problem is aggravated in the case of a dual-chamber pacer which includes an atrial sensing function because noise signals are more likely to mask the signals of interest.

While the two different types of electrode arrangements are best suited for the two different functions, prior art pacers have been inflexible in that the same unipolar or bipolar lead has been used for both pacing and sensing. While attention has been given to allowing the physician to determine whether a unipolar or bipolar configuration should be employed, whichever option he selects necessarily applies to both pacing and sensing. This is illustrated, for example, in the above-identified Patent No. 4,301,805. The pacer disclosed in this patent can operate in conjunction with either a unipolar or bipolar lead. A screw is provided in the device for establishing a connection to the annular ring at the proximal end of a bipolar lead; the setting of

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the screw determines whether the indifferent potential level in the pacer circuit within the case is connected to the annular ring of the indifferent electrode lead, or to the case itself. When a unipolar lead is employed, of course, there is no choice; the screw is set to that the internal indifferent potential level is applied to the case so that the case functions as the indifferent electrode. But when a bipolar lead is employed, the physician can select whether the indifferent potential level of the pacer circuit within the case is connected to the pacer case or to the indifferent electrode lead. However, whether a unipolar or a bipolar lead is utilized, and once the screw is set in one of its two operative positions even when a bipolar lead is employed, the pacing and sensing functions both employ the same electrode circuit. Either the case or one of the wires in the bipolar lead serves as the indifferent reference. A compromise must be made which favors either pacing or sensing.

It is a general object of my invention to provide a pacer which employs a bipolar lead extended to a heart chamber, but which while it utilizes the indifferent electrode lead for sensing nevertheless uses the pacer case as the indifferent reference for pacing.

Briefly, in accordance with the principles of my invention, the pacer case is connected to the internal indifferent reference in the pacer circuit. Any pacing pulse, atrial or ventricular, is generated by applying a stimulating potential to the respective atrial or stimulating electrode lead. The atrial or ventricular indifferent electrode lead is not connected to the pulse generator circuit.

When it comes to sensing, however, a sense amplifier has two inputs which are connected to the stimulating and indifferent electrode leads of the respective chamber. Thus sensing is accomplished by operating on the potential difference between the two electrodes of the bipolar lead, rather than on the potential difference between the stimulating electrode and the case.

As will become apparent below, a progammable option is provided by which the physician can control one of the inputs to the sense amplifier to be connected to the pacer case rather than to the indifferent lead. Thus if for some reason the physician does not desire bipolar lead sensing, he can "sense from the case" as well as "pace from the case", as has been done in the prior art with unipolar leads. The physician can select this programmable option even if the pacer is provided with a bipolar lead. As will also become apparent below, the pacer circuit also controls switches in the atrial and/or ventricular stimulating leads so that the conventional refractory-period timing may be achieved.

A further advantage of the system of my invention is that because an indifferent lead is not used for pacing, a secure connection of the indifferent lead to the pacer circuit is not vital; the indifferent lead is used only for sensing, and a broken connection will simply result in fixed-rate pacing when no heart activity is sensed. It is only when the indifferent electrode is used for pacing that a secure connection becomes vital because without it there is no closed circuit over which a pacing current can flow. What this means is that the typical grub-screw arrangement used for connecting the indifferent annular ring at the proximal end of the bipolar lead to the pacer circuit inside the case need not be employed; the connection is not critical, and a simple spring connection to the annular ring may be used. Also, the electrode leads may be quite thin; the resistance of each electrode lead, a function of how thin it is, can even be greater than 1 kilohm. The input impedance of a typical sense amplifier is quite high and thus there is little problem in having electrode leads of high resistance when it comes to sensing. It is only because of the pacing function that electrode leads should be low in resistance because the higher the resistance, the less current which can flow. Thus the use of my invention allows thinner electrode leads to be employed.

There is yet another advantage with the use of my invention, and it relates to the refractory-period timing in a dual-chamber pacer. When the atrium is paced, for example, a potential necessaily appears on the ventricular stimulating electrode. In order that the ventricular sense amplifier not interpret this signal as representing a ventricular beat, the sense amplifier must be disabled for a short period of time during and following generation of the atrial stimulating pulse. It is conventional practice to block ventricular sensing for a short time interval starting with the generation of the atrial stimulating pulse. Although the stimulating pulse itself may be only one millisecond in duration, the "refractory-period" timing is usually much longer. The flow of current through the body tissue stores charge in the tissue which effectively functions as an electrolytic capacitor. Until this charge dissipates and electrical balance is regained, the sense amplifier must be disabled or else it will become saturated. The refractory period should not be too long, however, because ventricular sensing is not possible during the interval. Prior art pacers have reduced the refractory period to as low as 16 milliseconds. But much of the electrolytic disruption during pacing takes place near the pacer case. By using two leads for sensing, both far removed from the case, much less time is required for the charge which affects sensing to dissipate. In accordance with the principles of my invention, a dual-chamber pacer may be constructed in which ventricular sensing can be disabled for as little as 8 milliseconds (there is really no valid reason for even attempting to

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reduce it still further), and atrial sensing can be disabled for as little as 10 milliseconds following the generation of a ventricular pacing pulse. (In the case of atrial sensing, the slightly longer refractory period is required due to the higher sensitivity of the atrial amplifier.) If the case is used for atrial sensing, the refractory period generally has to be as long as 35 milliseconds.

The electrode configuration of my invention should be contrasted with that disclosed in Patent No. 4,289,134, issued on September 15, 1981 and entitled "Tripolar Catheter Apparatus". This prior art patent teaches a technique for connecting three electrode leads to the two terminals of a conventional damand pacer. At least one resistor and one diode are incorporated in the lead arrangement, two of the electrodes are coupled to the chamber to be paced, and the third electrode is outside of this chamber. What results is pacing over the two electrodes coupled to the chamber, and sensing over one of these electrodes and the third. Thus there is neither pacing from the case, nor sening over two electrodes coupled to the chamber. As will become apparent below, I too contemplate sensing over two electrodes, one of which may not necessarily be coupled to the chamber whose activity is to be sensed. But in accordance with the principles of my invention, the case must be used for pacing. That has not been accomplished in the prior art except where the case has also been used for sensing, giving rise to the problems described above.

Further objects, features and advantages of my invention will become apparent upon consideration of the following detailed description in conjunction with the drawing, in which:

Figure 1 depicts the illustrative embodiment of my invention; and

Figure 2 illustrates various electrode placements which may be employed when using the pacer of Fig. 1.

The pacer of Fig. 1 is shown only schematically; only those elements required for an understanding of the present invention are shown in detail. For example, the conventional timing and logic circuits employed in a dual-chamber pacer are shown simply as a single block 44. All of the timing and control functions are not required for an understanding of the present invention. Insofar as the timing and logic circuits are concerned, a high potential at the output of atrial sense amplifier 30 is indicative of the sensing of atrial beat, and a high potential at the output of the ventricular sense amplifier 36 is indicative of a ventricular beat. When the timing and logic circuits determine that an atrial stimulating pulse is required, the input of atrial pulser 32 goes high; similarly, the timing and logic circuits apply a high potential to the input of ventricular pulser 34 whenever a ventricular stimulating pulse is required. These two inputs and outputs constitute the "interface" between the conventional timing and logic circuits, and the electrode arrangements to be described below. It should be noted that the timing and logic circuits are connected to the pacer case, as symbolized by the numeral 14. This is meant to indicate that there is a fixed connection of the pacer case to some point within the timing and logic circuits which is at the indifferent reference potential.

The pacer is also provided with a conventional program receiver 40 and parameter memory 42. In accordance with externally-generated signals, a physician may store several parameter values in the memory for adjusting such things as atrial and ventricular pulse widths, atrial-ventricular and ventricular-atrial delays, etc.—all as are known in the art. But in the illustrative embodiment of my invention, there are two other bits which are stored in the parameter memory. The SA bit determines whether atrial sensing utilizes the atrial indifferent electrode or the pacer case. As described above, while it is preferred to use the atrial indifferent, some physicians may wish to employ the pacer case for this purpose. Similarly, the SV bit determines whether the ventricular indifferent electrode or the pacer case is used during ventricular sensing.

Atrial indifferent electrode 10 is coupled through lead 70 and switch SA2 to the minus input of atrial sense amplifier 30. Atrial stimulating electrode 12 is coupled through electrode lead 72 and switch SA3 to the plus input of the amplifier. Switch SA3 is normally closed; it is opened only when a ventricular pacing pulse is being generated. Thus insofar as atrial sensing is concerned, the atrial stimulating electrode may be considered to be connected over lead 72 to the plus input of the atrial amplifier. The minus input of the amplifier is electrically connected either to the atrial indifferent electrode via switch SA2, or the pacer case via switch SA1. If the SA bit is a 0, then switch SA2 is closed and switch SA1 is open, and atrial sensing employs the atrial indifferent electrode. On the other hand, if the SA bit is a 1, switch SA1 is closed and switch SA2 is open, and the minus input of the atrial amplifier is connected to the pacer case.

An identical arrangement is provided for connecting ventricular stimulating electrode 22 and ventricular indifferent electrode 20 via respective leads 74, 76 to the plus and minus inputs of ventricular sense amplifier 36. In this case, the SV bit determines which of switches SV1 and SV2 is closed, and whether ventricular sensing employs the pacer case or the ventricular indifferent electrode. Switch SV3 is normally closed, as is switch SA3: switch SV3 is opened in order to disable the ventricular sense amplifier only when an atrial stimulating pulse is being generated.

When the timing and logic circuits 44 de-

termine that an atrial stimulating pulse is required, the output of amplifier 32 goes high. The pulse is applied directly to lead 72, and current flows between the atrial stimulating electrode and the pacer case. Monostable multivibrator 50 is triggered at the start of the atrial stimulating pulse; the ouput of the multivibrator goes high to hold switch SV3 open for ten milliseconds as described above so that the ventricular sense amplifier does not misinterpret an atrial stimulating pulse as a ventricular beat. Similarly, ventricular pulser 34 pulses its output when a ventricular stimulating pulse is required, current flowing between the ventricular stimulating electrode 22 and the pacer case. When the output of the ventricular pulser first goes high, monostable multivibrator 52 is triggered so that switch SA3 is held open for 8 milliseconds; in this way, the atrial sense amplifier does not misinterpret any activity on the atrial stimulating electrode as representing an atrial beat.

It is thus apparent that while the use of a bipolar lead for each chamber allows sensing to employ both electrodes (provided the respective SA or SV bit is a 0), the indifferent electrode is not in the corresponding pacing circuit. Instead, the current which is used to pace either chamber flows between the respective stimulating electrode and the pacer case.

Although a dual-chamber pacer is illustrated in Fig. 1, as mentioned above it is to be appreciated that the same basic type of electrode configuration can be emloyed in a single-chamber pacer. It is also possible to provide a bipolar lead arrangement for one chamber of a dual-chamber pacer, as illustrated in Fig. 1, with a unipolar lead for the other chamber. Still another possibility is that symbolized by the dashed line 78. If it is desired to employ only one indifferent electrode, i.e., one unipolar lead and one bipolar lead, but to have that single indifferent electrode involved in both sensing functions, leads 70 and 76 may be connected together at the pacer. In such a case, only three wires would have to be extended to the heart, two in the form of a bipolar lead and one in the form of a unipolar lead.

Fig. 2 depicts various electrode placements. It should be borne in mind that a typical bipolar lead consists of two helically-wound wires, one around the other, separated by insulation. The outer wire is encased in a plastic sheath, and it serves as the indifferent electrode. In order to "couple" the indifferent electrode to the heart, all that is required is to cut away a region of the plastic sheath around the indifferent electrode and to connect the electrode at that point to an annular ring, as is known in the art.

The pacer itself is depicted in Fig. 2 as having a metallic case 14 and a connector assembly 80. Two bipolar leads are employed, wires 70, 72 comprising the bipolar atrial lead, and wires 74, 76 comprising the bipolar ventricular lead. The numerals 12 and 22 represent respectively the atrial and ventricular stimulating electrodes depicted in Fig. 1. The symbol 12 represents the position of the atrial indifferent electrode and the symbol 14 represents the position of the ventricular indifferent electrode, where a different indifferent electrode is used for each chamber. In the event only a single indifferent electrode is used, i.e., the connection symbolized by dashed line 78 in Fig. 1 is utilized, that single indifferent electrode may be placed in a variety of positions, some of which are illustrated by the symbols 11, 13 and 15. Positions 12 and 14 are too close to one of the stimulating electrodes to allow the respective indifferent electrode to be employed in the other sensing circuit. Thus if a single indifferent electrode is utilized at position 12, ventricular sensing should be at the case, and the SV bit should be a 1. Similarly, if the single indifferent electrode is at position 14, atrial sensing should be at the case, and the SA bit should be a 1. Other combinations are also possible; for example, it is possible to use two indifferent electrodes at positions 12 and 13. In the event only a single indifferent electrode is employed, the preferred placement of the electrode is at position 11

Although the invention has been described with reference to a particular embodiment, it is to be understood that this embodiment is merely illustrative of the application of the principles of the invention. Numerous modifications may be made therein and other arrangements may be devised without departing from the spirit and scope of the invention.

CLAIMS

1. A heart pacer comprising lead means terminating in at least two electrodes, a case, and circuit means inside said case having a reference potential coupled to said case, said circuit means including means for sensing heart activity in the form of a potential difference appearing across said two electrodes, said circuit means further including means for operating in accordance with the sensed heart activity to stimulate heart activity by applying a current pulse between one of said electrodes and said case.

2. A heart pacer in accordance with claim 1 wherein said lead means includes two leads, a first of which terminates in at least two electrodes and the second of which terminates in at least one electrode.

3. A heart pacer in accordance with claim 2 wherein said sensing means includes first means for sensing a potential difference appearing across the two electrodes which terminate said first lead, and second means for sensing the potential difference which appears across said at least one electrode which

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terminates said second lead and a point of reference potential.

4. A heart pacer in accordance with claim 3 wherein said second lead includes only one wire terminating in only one electrode, and said second means senses the potential difference which appears across said one electrode and one of the two electrodes which terminate said first lead.

5. A heart pacer in accordance with claim 2 further including means under external programmable control for selectively controlling and sensing means to sense a potential difference which appears across said pacer case and one of the two electrodes which terminate said first lead.

6. A heart pacer in accordance with claim 1 further including means under external programmable control for selectively controlling said sensing means to sense a potential difference which appears across said pacer case and one of said two electrodes.

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